

**Guney Biomedikal Saglik Urunleri as**  
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**34524 ISTANBUL**  
**Turkey**

**Your notice of**  
 14-07-2020

**Your reference**

**Date**  
 14-08-2020

## Analysis Report 20.04471.01

Required tests :

<b>EN 14683 (2019) + AC (2019)</b>	<b>EN 14683 - annex C (2019) + AC (2019)</b>	<b>Medical face masks - Breathability (differential pressure)</b>
<b>EN 14683 (2019) + AC (2019)</b>	<b>ISO 22609 (2004)</b>	<b>Medical face masks - Splash Test</b>
<b>EN 14683 (2019) + AC (2019)</b>	<b>EN 14683 - annex B (2019) + AC (2019)</b>	<b>Bacterial filtration efficiency</b>
<b>EN 14683 (2019) + AC (2019)</b>	<b>EN 14683 - §5.2.5 (2019) AC (2019)</b>	<b>Microbial cleanliness on masks</b>

Sample id	Information given by the client	Date of receipt
T2015723	1. TYPE IIR 2. LAYERS 3. FULL ULTRASONIC 4. WITH NOSE SUPPORT 5. LATEX FREE 6. DISPOSABLE	14-07-2020

**Christine Remi**  
**Order responsible**

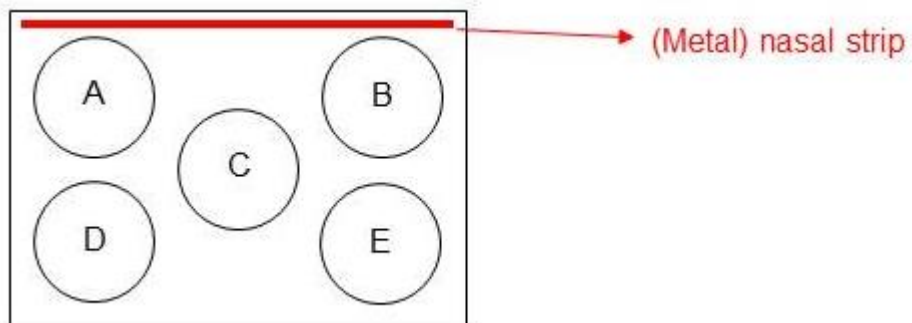
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 In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.

**Reference:**      **T2015723 - 1. TYPE IIR**  
                       **2. LAYERS**  
                       **3. FULL ULTRASONIC**  
                       **4. WITH NOSE SUPPORT**  
                       **5. LATEX FREE**  
                       **6. DISPOSABLE**

**Medical face masks - Breathability (differential pressure)**

Date of ending the test	16-07-2020
Standard used	EN 14683 - annex C (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks :	5
Number of areas per mask	5 (see figure)
Dimension of the areas :	Disc whose diameter is 2.5 cm
Surface areas :	4.9 cm <sup>2</sup>
Flow rate :	8 l/min.
Direction of the air flow :	From the inside of the mask to the outside
Masks conditioning :	21 ± 5°C and 85 ± 5% RH

Figure : Distribution of the areas in the mask





**Results**       $\Delta P$

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	15.5	21.2	23.8	13.2	25.9
Area B	23.4	25.9	23.8	21.4	21.4
Area C	16.9	18.3	19.8	15.1	15.1
Area D	19.6	17.5	15.3	18.7	16.7
Area E	18.7	19.8	19.4	15.1	13.9
<b>Average <math>\Delta P</math> (Pa/cm<sup>2</sup>)</b>	<b>18.8</b>	<b>20.5</b>	<b>20.4</b>	<b>16.7</b>	<b>18.6</b>

**Note** :

*The performance requirements for medical face masks according to EN 14683 (2019) + AC (2019) is :*

Test	Type I	Type II	Type IIR
<i>Differential pressure (Pa/cm<sup>2</sup>)</i>	< 40	< 40	< 60

**Reference: T2015723 - 1. TYPE IIR**  
**2. LAYERS**  
**3. FULL ULTRASONIC**  
**4. WITH NOSE SUPPORT**  
**5. LATEX FREE**  
**6. DISPOSABLE**

**Microbial cleanliness on masks**

Date of ending the test 11-08-2020  
Standard used EN 14683 - §5.2.5 (2019) AC (2019)  
Product standard EN 14683 (2019) + AC (2019)

Number of tested masks 5  
Extraction liquid Peptone 1g/l, NaCl 5g/l & Tween 20 2g/l  
Extraction volume 300 ml  
Extraction time 5 min.  
Counting technique Membrane filtration  
Filtration volume 100 ml  
Culture media TSA (Tryptic Soy Agar)  
SDA (Sabouraud Dextrose Agar with chloramphenicol)

Incubation conditions 3 days at 30°C (TSA)  
7 days at 20-25°C (SDA)

**Results**

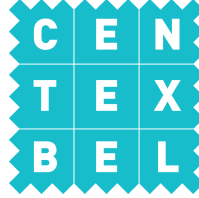
# Mask	Mask weight (g)	CFU*/mask		Microbial cleanliness	
		<i>Aerobic microbial count (bacteria)</i>	<i>Fungi count (SDA)</i>	$\Sigma$ CFU/mask	$\Sigma$ CFU/g
1	3.30	93	15	108	33
2	3.27	51	3	54	17
3	3.31	24	15	39	12
4	3.29	48	45	93	29
5	3.33	30	15	45	14



**Note :**

*The performance requirements for medical face masks according to EN 14683 (2019) + AC (2019) is :*

<b>Test</b>	<b>Type I</b>	<b>Type II</b>	<b>Type IIR</b>
<i>Microbial cleanliness (cfu/g)</i>	$\leq 30$	$\leq 30$	$\leq 30$



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**Turkey**

**Your notice of**  
14-09-2020

**Your reference**

**Date**  
12-10-2020

## Analysis Report 20.05563.01

Required tests :

**EN 14683 (2019) + AC  
(2019)**

**EN 14683 - annex B (2019)  
+ AC (2019)**

**Bacterial filtration efficiency**

**EN 14683 (2019) + AC  
(2019)**

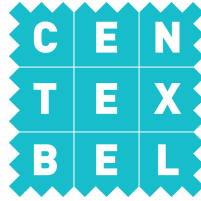
**ISO 22609 (2004)**

**Medical face masks - Splash Test**

Sample id	Information given by the client	Date of receipt
T2019717	Lot W820-01	14-09-2020

Sylvie Niessen  
Order responsible

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**Reference: T2019717 - Lot W820-01**

**Bacterial filtration efficiency**

Date of ending the test	09-10-2020
Standard used	EN 14683 - annex B (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks :	5
BFE Area tested :	$\pm 49 \text{ cm}^2$
Masks conditioning :	$21 \pm 5^\circ\text{C}$ and $85 \pm 5\% \text{ RH}$
Side of the mask in contact with the bacterial challenge :	Inner side
Challenge bacterial strain used :	<i>Staphylococcus aureus</i> ATCC6538
Bacterial challenge per test :	1700 - 3000 CFU
Total test time :	1 min. delivering challenge + 1 min. without challenge (air flow continuing)
Flow rate :	28.3 l/min.
Positive control	Tests performed with no filter material in the air stream
Negative control	Test performed without challenge



## Results

B = Bacterial filtration efficiency (%)

$$B = \frac{(C - T)}{C} \times 100$$

With C = mean of the total plate counts for the positive control runs  
T = total count for the tested mask

# Mask	B (%)
1	99.9
2	> 99.9*
3	> 99.9
4	99.8
5	> 99.9*

\* no detected colonie on any of the Andersen sampler plates

Mean particle size of the bacterial challenge aerosol : 2.7 µm

### Controls

Mean positive controls 3194 CFU  
Negative control < 1 CFU

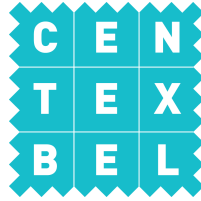
Remark : The mean "positive controls" is slightly too high but acceptable considering the very good obtained results.

### Note :

*The performance requirements for medical face masks according to EN 14683 (2019) + AC (2019) is :*

Test	Type I	Type II	Type IIR
(BFE) Bacterial filtration efficiency (%)	≥ 95	≥ 98	≥ 98





**Reference: T2019717 - Lot W820-01**

**Medical face masks - Splash Test**

Date of ending the test	06-10-2020
Standard used	ISO 22609 (2004)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks :	32
Blood surface tension	$42 \pm 2$ dynes/cm
Volume of the delivered blood	2 ml
Distance "canula-mask"	$30 \pm 1$ cm
Side of the mask "impacted"	Outer side
Masks conditioning :	$21 \pm 5^\circ\text{C}$ and $85 \pm 5\%$ RH

**Results**

**Blood pressure tested 16.0 kPa**

**Controls**

Blood visualisation on the mask	OK
Calibration procedure	OK
Control of the blood volume delivered (2 ml)	
- before the test :	OK
- after 16 masks :	OK
- after 32 masks :	OK